IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

JESSICA FARSON,

Plaintiff,

v.

COOPERSURGICAL, INC., et al.,

Defendants.

CASE NO. 3:22 CV 716

JUDGE JAMES R. KNEPP II

MEMORANDUM OPINION AND ORDER

INTRODUCTION

Currently pending in this products liability case are Motions to Dismiss Plaintiff's Amended Complaint from Defendants CooperSurgical, Inc. (Doc. 40), Cooper Companies, Inc. (Doc. 38), Utah Medical Products, Inc. (Doc. 39), and Femcare, Ltd. (Doc. 52). Plaintiff opposed all four motions, and all Defendants replied. Jurisdiction is proper under 28 U.S.C. § 1332. For the following reasons, the Court grants all four motions and dismisses this case.

BACKGROUND

Plaintiff Jessica Farson underwent a tubal ligation surgery in 2008. (Doc. 35, at 14). The claims in her Amended Complaint arise from the use of a product called Filshie Clips during that surgery. *Id.*

Filshie Clips are "intended to cause bilateral occlusion (blockage) of the fallopian tubes" by "applying a titanium clip with silicone rubber lining around each of the fallopian tubes." *Id.* at 4-5. Defendant Femcare, Ltd. is the manufacturer of Filshie Clips. *Id.* at 5. Femcare, Ltd., a foreign company, is owned by Defendant Utah Medical Products, Inc. *Id.* at 3. Defendant CooperSurgical, Inc., is a subsidiary of Defendant Cooper Companies, Inc. *Id.* Filshie Clips obtained Conditional

Premarket Approval ("PMA") in 1996 from the Food and Drug Administration ("FDA") and are classified as a Class III medical device. *Id.* at 5-6. Plaintiff states Defendants CooperSurgical, Inc., Femcare, Ltd., and Utah Medical Products, Inc., "singularly and in combination, designed, manufactured, sold and distributed Filshie Clips and related equipment utilized in Plaintiff's tubal ligation." *Id.* at 7.

It is possible for Filshie Clips to migrate in the body after being used in a tubal ligation surgery. *Id.* at 9. During the premarket approval process, "it was reported to the FDA that the Filshie Clip System had a migration incidence of [0].13 [percent]." *Id.* at 10. Plaintiff alleges Defendants knew at the time that such migration actually occurs in more than 25 percent of cases. *Id.* at 9.

At the time of her surgery, Plaintiff received and signed a disclosure and consent form regarding risks and hazards associated with a tubal ligation. *Id.* at 14. "No mention was made of the risk of migration and the appurtenant damages that could be caused by the Filshie Clips." *Id.* Plaintiff also states, "the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips." *Id.*

In September 2021, Plaintiff underwent X-ray and CT scans for an unrelated issue which revealed "one Filshie Clip had migrated and [e]mbedded itself in her pelvic artery[,] and the other had migrated and [e]mbedded itself in her abdomen." *Id.* In January 2022, she underwent surgery to remove the clips; the surgery was unsuccessful, as "both clips posed too much of a threat in their current position to be safely removed." *Id.*

STANDARD OF REVIEW

On a motion to dismiss under Federal Civil Rule 12(b)(2), the plaintiff bears the burden of establishing personal jurisdiction. *Walker v. Concoby*, 79 F. Supp. 2d 827, 829 (N.D. Ohio 1999).

When personal jurisdiction is challenged under Federal Civil Rule 12(b)(2), the Court "will construe the facts in a light most favorable to the nonmoving party." *Bird v. Parsons*, 289 F.3d 865, 871 (6th Cir. 2002). "Once the defense has been raised, then the plaintiff must sustain [her] burden of proof in establishing jurisdictional facts through sworn affidavits and competent evidence." *Hammons v. Lasik Vision Inst., LLC*, 2006 WL 2583162, at *3 (W.D. Tenn.). A *prima facie* showing of personal jurisdiction is all that is required. *See Bird*, 289 F.3d at 871; *see also Theunissen v. Matthews*, 935 F.2d 1454, 1459 (6th Cir. 1991).

On a motion to dismiss under Federal Civil Rule 12(b)(6), the Court tests the complaint's legal sufficiency. The Court construes the complaint in the light most favorable to the plaintiff, accepts all factual allegations as true, and determines whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a complaint need not contain "detailed factual allegations," it requires more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Id.* at 555. The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

DISCUSSION

Plaintiff asserts products liability claims of design defect, manufacturing defect, and failure to warn against all Defendants. (Doc. 35, at 2). Defendants Cooper Companies, Inc. ("Cooper"), Utah Medical Products, Inc. ("Utah"), and Femcare, Ltd. ("Femcare"), move to dismiss the complaint for lack of personal jurisdiction. (Doc. 38, at 1; Doc. 39, at 1; Doc. 52, at 1). Defendants Cooper, Utah, and CooperSurgical, Inc. ("CooperSurgical"), move to dismiss the complaint for

failure to state a claim based on "shotgun pleading". (Doc. 38, at 1; Doc. 39, at 1; Doc. 40, at 1). All four Defendants move to dismiss the complaint based on preemption grounds and failure to state a manufacturing defect claim. (Doc. 38, at 1; Doc. 39, at 1; Doc. 40, at 1; Doc. 52, at 1).[1] The Court grants the motions by Cooper, Utah, and Femcare for lack of jurisdiction and grants the motion by CooperSurgical on preemption grounds and for failure to state a claim.

Personal Jurisdiction

Cooper, Utah, and Femcare move to dismiss the complaint for lack of personal jurisdiction. "A federal court sitting in diversity may not exercise jurisdiction over a defendant unless (1) courts of the forum state would be authorized to do so by state law[,] and (2) any such exercise of jurisdiction [would] be compatible with the due process requirements of the United States Constitution." *Conn v. Zakharov*, 667 F.3d 705, 711 (6th Cir. 2012).

State Law

Ohio's long-arm statute allows courts to exercise specific personal jurisdiction over defendants in cases that arose from any of the following actions done by the defendant:

> (1) Transacting any business in this state;
>
> (2) Contracting to supply services or goods in this state;
>
> (3) Causing tortious injury by an act or omission in this state;
>
> (4) Causing tortious injury in this state by an act or omission outside this state if the person regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state;
>
> (5) Causing injury in this state to any person by breach of warranty expressly or impliedly made in the sale of goods outside this state when the person might

1. During briefing, all parties additionally filed multiple notices of supplemental authority from cases in other federal districts against Defendants; these non-controlling authorities addressed jurisdiction and preemption issues according to law in their states and federal districts. (Docs. 59, 60, 63, 64, 66, 67, 69).

> reasonably have expected such person to use, consume, or be affected by the goods in this state, provided that the person also regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state;
>
> (6) Causing tortious injury in this state to any person by an act outside this state committed with the purpose of injuring persons, when the person might reasonably have expected that some person would be injured thereby in this state;
>
> (7) Causing tortious injury to any person by a criminal act, any element of which takes place in this state, which the person commits or in the commission of which the person is guilty of complicity;
>
> (8) Having an interest in, using, or possessing real property in this state;
>
> (9) Contracting to insure any person, property, or risk located within this state at the time of contracting.

Ohio Rev. Code § 1207.382(A). As of April 2021, the long-arm statute also provides that:

> In addition to a court's exercise of personal jurisdiction under division (A) of this section, a court may exercise personal jurisdiction over a person on any basis consistent with the Ohio Constitution and the United States Constitution.

Ohio Rev. Code § 1207.382(C). Ohio's appellate courts and Supreme Court have not yet interpreted the new provision in a written decision. Some federal district courts in Ohio have decided "Ohio's long-arm statute now extends personal jurisdiction to the fullest extent that the U.S. Constitution permits." *AmaTech Grp. Ltd. v. Fed. Card Serv., LLC*, 2022 WL 44674, at *5 (S. D. Ohio) (citing *C.T. v. Red Roof Inns, Inc.*, 2021 WL 2942483, at *10 (S.D. Ohio); *Smith v. Swaffer*, 566 F. Supp. 3d 791, 806 (N.D. Ohio 2021); and *NOCO Co. v. Shenzhen Valuelink E-Com. Co.*, 550 F. Supp. 3d 488, 493 (N.D. Ohio 2021)). One other federal district court concluded the purpose of new provision "is merely to allow for 'general jurisdiction' over non-resident defendants in appropriate circumstances", rather than specific jurisdiction. *AmaTech*, 2022 WL 44674, at *5 (citing *Premier Prop. Sales Ltd. v. Gospel Ministries Int'l, Inc.*, 539 F. Supp. 3d 822,

827 n.2 (S.D. Ohio 2021)). Under this interpretation, a plaintiff "asserting that a court has specific jurisdiction over a defendant must still demonstrate their claim arose from one of the enumerated factors." *Premier Prop. Sales*, 539 F. Supp. 3d at 827 n.2.

The Ohio Revised Code provides that amendment of a statute "does not . . . affect the prior operation of the statute or any prior action taken thereunder." Ohio Rev. Code § 1.58(A)(1). Plaintiff filed this suit on April 4, 2022, after the amendment took effect. *See* Doc. 1. Defendants, however, argue that because "the events that gave rise to the [complaint] all took place well before the amendment", division (C) of the long-arm statute does not apply. (Doc. 38-2, at 11).

Plaintiff does not respond to this argument, but rather argues this Court has specific personal jurisdiction over the Defendants as defined by the division (A) list of actions generally, for Femcare, and under an "alter ego" theory, for Cooper and Utah.

Personal Jurisdiction Over Femcare Under Long-Arm Statute

Plaintiff argues that Femcare meets at least one of the first four provisions of division (A) of Ohio's long-arm statute:

> (1) Transacting any business in this state;
>
> (2) Contracting to supply services or goods in this state;
>
> (3) Causing tortious injury by an act or omission in this state;
>
> (4) Causing tortious injury in this state by an act or omission outside this state if the person regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state[.]

(Doc. 55, at 15 (citing Ohio Rev. Code § 2307.382)). Plaintiff cites no evidence in support of this statement. The remainder of Plaintiff's argument regarding this Court's jurisdiction over Femcare concerns constitutional due process considerations, not the long-arm statute requirements. *Id.* at 16-23.

Femcare argues that "Plaintiff has failed to provide any evidence or basis to show Ohio's long-arm statute has been satisfied." (Doc. 57, at 6). "Ohio's long-arm statute has less reach than the Due Process Clause because of a more restrictive interpretation of the 'arising from' prong." *Brunner v. Hampson*, 441 F.3d 457, 466 (6th Cir. 2006). "[P]ersonal jurisdiction will be conferred *only if* the defendant's conduct *in Ohio*, as enumerated by the long-arm statute, is the 'proximate cause' of the cause of action." *United States ex rel. South Shore Elec., Inc. v. P & E Constr., LLC*, 2019 WL 1205447, at *3 (N.D. Ohio) (citing *Brunner*, 441 F.3d at 465-66) (emphasis in original).

Because Plaintiff has not set forth any evidence to support the assertion Femcare meets a prong of the long-arm statute, to the extent the Ohio long-arm statute can only be met via the division (A) factors, the Court does not have personal jurisdiction over Femcare.

"Alter Ego" Theory

Plaintiff argues jurisdiction over Cooper and Utah is proper via the alter ego theory of jurisdiction permitted by the Sixth Circuit in Ohio. (Doc. 44, at 23).[2] This theory provides that "a non-resident parent corporation is amenable to suit in the forum state if the parent company exerts so much control over the subsidiary that the two do not exist as separate entities but are one and the same for purposes of jurisdiction." *Estate of Thomson ex rel. Estate of Rakestraw v. Toyota Motor Corp. Worldwide*, 545 F.3d 357, 362 (6th Cir. 2008). Ohio courts determine whether a parent company exerts such control over a subsidiary by considering "factors such as whether (1) corporate formalities are observed, (2) corporate records are kept, and (3) the corporation is

2. Defendants argue that because Plaintiff did not set forth her alter ego theory in the Complaint, it must fail. (Doc. 48, at 7; Doc. 49, at 4). But it is appropriate for the Court, in evaluating personal jurisdiction, to "consider all pleadings, motions, and facts presented". *Microsys Comp., Inc. v. Dynamic Data Sys., LLC*, 2006 WL 2225821, at *4 (N.D. Ohio) (*citing Neogen Corp. v. Neo Gen Screening, Inc.*, 282 F.3d 883, 887 (6th Cir. 2002); *Malone v. Windsor Casino Ltd.*, 14 F. App'x 634, 636 (6th Cir. 2001)).

financially independent." *Id.* The Sixth Circuit additionally considers "(1) sharing the same employees and corporate officers; (2) engaging in the same business enterprise; (3) having the same address and phone lines; (4) using the same assets; (5) completing the same jobs; (6) not maintaining separate books, tax returns and financial statements; and (7) exerting control over the daily affairs of another corporation." *Id.* at 362-63. The alter ego theory of jurisdiction is essentially a version of "'pierc[ing] the corporate veil' of the subsidiary and imput[ing] personal jurisdiction from the subsidiary to the parent." *Invacare Corp. v. Sunrise Med. Holdings, Inc.*, 2004 WL 3403352, at *7 (N.D. Ohio).

Plaintiff posits that CooperSurgical, subsidiary of parent company Cooper, is Cooper's alter ego. (Doc. 44, at 24). CooperSurgical has not contested this Court's jurisdiction over it. Plaintiff cites in support of this contention: (1) shared leadership between Cooper and CooperSurgical and (2) press releases issued by Cooper on behalf of CooperSurgical regarding acquisitions, which Plaintiff argues indicate "financial entanglements where a parent company would control and be financially responsible for the subsidiaries' acquisitions or corporate structure." *Id.* at 28.

These facts are not sufficient for the Court to consider CooperSurgical an alter ego of Cooper. Plaintiff "only alleges facts regarding ownership that partially satisfy a few different factors." *Anwar v. Dow Chemical Co.*, 876 F.3d 841, 850 (6th Cir. 2017). That Cooper released press statements for CooperSurgical does not necessarily impute the financial entanglements Plaintiff implies. "Even where the officers and directors of a subsidiary and parent corporation overlap, that factor alone is not enough to warrant a finding that the subsidiary is an alter-ego of the parent corporation." *Garlock v. Ohio Bell Tel. Co. Inc.*, 2014 WL 2006781, at *6 (N.D. Ohio).

Plaintiff additionally argues Utah, parent company of foreign subsidiary Femcare, is Femcare's alter ego. (Doc. 45, at 29). In support of this argument, Plaintiff cites: (1) Utah's marketing materials, which state that Filshie Clips are "a product of both Utah Medical and Femcare" and that Utah is the appropriate contact for Filshie Clips in the United States; (2) shared leadership between Femcare and Utah; and (3) Utah's annual 10K reports, which include the information that Utah absorbed Femcare's debt upon acquisition and that Filshie Clips, manufactured by Femcare, routinely account for one third of Utah's total sales. (Doc. 45, at 31).

While Utah's absorption of some Femcare debt is slightly stronger evidence of financial interdependence, Plaintiff presents no evidence regarding commingled accounts, books, or financial statements between the companies; lack of corporate formalities or records; use of the same assets; identical addresses or phone lines; or control over daily corporate activities. There is not enough evidence to conclude "the parent company exerts so much control over the subsidiary that the two do not exist as separate entities but are one and the same". *Microsys Comp., Inc., v. Dynamic Data Sys., LLC*, 2006 WL 2225821, at *5 (N.D. Ohio). Additionally, as discussed above, Plaintiff set forth no evidence to support the assertion that Femcare meets the long-arm statute requirements itself. The Court will not consider Utah an alter ego of Femcare.

Plaintiff asserts this Court has personal jurisdiction under state law over Cooper and Utah only via the alter ego theory. To the extent the Ohio long-arm statute can only be met via the division (A) factors, the Court does not have personal jurisdiction over Cooper and Utah.

Constitutional Requirements

The Court would ordinarily stop its jurisdictional analysis upon concluding the first personal jurisdiction requirement (comportment with the long-arm statute) is not met. *See Brunner*, 441 F.3d at 463. Because there is legal uncertainty regarding interpretation Ohio's recent

amendment of the statute, under which it is possible personal jurisdiction extends to the limits of constitutional due process, this Court analyzes the constitutional issues as well.

"The Due Process Clause requires that [a nonresident defendant] have sufficient minimum contacts with the forum state so that finding personal jurisdiction does not offend traditional notions of fair play and substantial justice." *Conn v. Zakharov*, 667 F.3d 705, 712 (6th Cir. 2012) (citing *Third Nat'l Bank v. WEDGE Grp., Inc.*, 882 F.2d 1087, 1089 (6th Cir. 1998), *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). The Sixth Circuit determines whether a finding of specific personal jurisdiction comports with this requirement via a three-part test:

> First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Means v. United States Conf. of Cath. Bishops, 836 F.3d 643, 649 (6th Cir. 2016).

Defendants Cooper, Utah, and Femcare each argue Plaintiff cannot show they "purposefully avail[ed] [themselves] of the privilege of acting in the forum state." *See* Doc. 38-2, at 9; Doc. 39-2, at 9; Doc. 52, at 9.

A defendant meets the purposeful availment requirement when "the defendant's contacts with the forum state 'proximately result from actions by the defendant himself that create a "substantial connection" with the forum [s]tate'". *CompuServe, Inc. v. Patterson*, 89 F.3d 1257, 1263 (6th Cir. 1996) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474-75 (1985)). This does not mean a defendant "must be physically present in the forum state", but it does mean a commercial-actor defendant's efforts must be "purposefully directed toward the residents of [the forum s]tate". *Id.* at 1264. A defendant must, however, "do more than merely place a product into the stream of commerce." *Parker v. Winwood*, 938 F.3d 833, 840 (6th Cir. 2019). The Sixth Circuit

uses the stream of commerce "plus" approach to purposeful availment, under which theory "the placement of a product into the stream of commerce, without more, is not an act of the defendant purposefully directed toward the forum [s]tate." *Asahi Metal Indus. Co., Ltd. v. Super. Ct. of Cal., Solano Cnty.*, 480 U.S. 102, 112 (1987) (O'Connor, J., plurality); *see also Bridgeport Music, Inc. v. Still N The Water Publ'g*, 327 F.3d 472, 480 (6th Cir. 2003) ("we make clear today our preference for Justice O'Connor's stream of commerce 'plus' approach"). This something "more" in addition to placing a product into the stream of commerce can be, "for example, designing the product for the market in the forum [s]tate, advertising in the forum [s]tate, establishing channels for providing regular advice to customers in the forum [s]tate, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum [s]tate." *Asahi*, 480 U.S. at 112.

In her opposition brief, Plaintiff asserts no contact by Cooper with Ohio other than its ownership of CooperSurgical in support of Plaintiff's alter ego theory. (Doc. 44, at 17). In her Complaint, while Plaintiff alleges "the Defendants conducted and continue to regularly conduct substantial business within the state of Ohio which included and continues to include[] the research, safety surveillance, manufacture, sale, distribution and/or marketing of Filshie Clips which are distributed through the stream of interstate and intrastate commerce in the state of Ohio" (Doc. 35, at 4), Plaintiff sets forth no factual statements regarding Cooper's actions in Ohio or directed specifically toward Ohio which are not legal conclusions couched as facts. *Theunissen*, 935 F.2d at 1458 ("the plaintiff . . . must, by affidavit or otherwise, set forth specific facts showing that the court has jurisdiction").

Plaintiff likewise asserts no conduct by Utah specifically targeting Ohio. In her Complaint, Plaintiff states "Defendants[] CooperSurgical, Femcare[], and Utah Medical Products[] singularly and in combination[] designed, manufactured, sold and distributed Filshie Clips and related

equipment". (Doc. 35, at 7). In her opposition brief, Plaintiff cites evidence that Utah "has sold, marketed, and distributed Filshie Clips in the United States" and that Utah "touts the product as 'Globally Recognized and Recommended' . . . [which makes it] reasonable to believe the Filshie Clips are being used in the state of Ohio and likely in significant numbers." (Doc. 45, at 23-24. While Plaintiff states a declaration by Utah's CEO "admits . . . that Utah Medical . . . currently sells, markets, and distributes Filshie Clips in Ohio" (Doc. 45, at 23), the cited declaration refers to selling, marketing, and distributing Filshie Clips nationally. (Doc. 39-1, at 1-2).

Finally, Plaintiff asserts Femcare "manufactured and knowingly[] distributed [Filshie Clips] to the residents of Ohio", but cites only evidence that Femcare did business in the United States as a whole. (Doc. 55, at 22). Plaintiff argues Femcare did more than place its product into the stream of commerce by "maintain[ing] software systems that allow[] it to track every single Filshie Clip that has ever been sold", "work[ing] collaboratively with its distributors to sell its products in the United States", and remaining obligated to adhere to FDA guidelines in the United States. *Id.* at 23-24. None of this conduct is directed specifically at Ohio. Plaintiff cites no controlling caselaw for the proposition that a foreign company who sells a product throughout the United States at large meets stream of commerce "plus" requirements; she cites only cases from federal circuits which permit the less restrictive stream of commerce theory. (Doc. 55, at 25 (citing *In re Depuy Orthopaedics, Inc.*, 888 F.3d 753 (5th Cir. 2018) and *Collett v. Olympus Medical Sys. Corp.*, 437 F. Supp. 3d 1272 (M.D. Ga. 2020))). In the lone Sixth Circuit case Plaintiff cites regarding personal jurisdiction over foreign manufacturers, the defendant "conceded, for purposes of its motion, that it had purposely availed itself of the benefits and protections offered by the State of Ohio." *Malone v. Stanley Black & Decker, Inc.*, 965 F.3d 499, 501 (6th Cir. 2020).

Plaintiff presents insufficient factual matter to permit this Court to exercise jurisdiction over Cooper, Femcare, or Utah under constitutional due process requirements in the Sixth Circuit. As such, even under an interpretation of Ohio's long-arm statute as extending personal jurisdiction over out-of-state defendants to constitutional limits, none of these Defendants is subject to this Court's jurisdiction.

Jurisdictional Discovery

Plaintiff moves in the alternative for permission to conduct jurisdictional discovery against Cooper and Utah. (Doc. 44, at 29; Doc. 45, at 32). "[W]hether or not to allow discovery prior to deciding a motion to dismiss for lack of jurisdiction is within the discretion of the district court." *KNC Investments, LLC v. Lane's End Stallions, Inc.*, 579 F. App'x 381, 385 (6th Cir. 2014) (citing *Chrysler Corp. v. Fedders Corp.*, 643 F.2d 1229 (6th Cir. 1981)). While Plaintiff "must be given an opportunity to secure and present relevant evidence to the existence of jurisdiction" when such jurisdiction is challenged, "they must 'explain what evidence relevant to subject matter jurisdiction they [would be] denied from obtaining." *C.H. ex rel. Shields v. United States*, 818 F. App'x 481, 484 (6th Cir. 2020) (quoting *Gilbert v. Ferry*, 401 F.3d 411, 415 (6th Cir. 2005)). Plaintiff is not entitled to such discovery "if she cannot, at a minimum . . . give the district court a reasonable basis to expect that discovery would reveal evidence that supports the claimed jurisdiction." *Shields*, 818 F. App'x at 484 (cleaned up).

Plaintiff does not identify what evidence she expects to find which might grant this Court jurisdiction over Cooper or Utah. She states only that "the party that knows most about [Cooper's] corporate structure is Cooper Companies itself" (Doc. 44, at 29), and likewise for Utah (Doc. 45, at 32). These statements do not "offer any factual basis for her allegations" of jurisdiction. *Shields*, 818 F. App'x at 484; *see also A.O. Smith Corp. v. United States*, 774 F.3d 359, 369-70 (6th Cir.

2014) (the district court did not abuse its discretion in denying jurisdictional discovery where plaintiffs speculated that documents "might" contain relevant jurisdictional information). The Court therefore denies Plaintiff's requests for jurisdictional discovery in this case.

Preemption

Remaining Defendant CooperSurgical argues Plaintiff's claims against it are preempted both expressly and impliedly by the Federal Food, Drug, and Cosmetic Act (FDCA) and Plaintiff's manufacturing defect claim fails the Rule 12(b)(6) standard. (Doc. 40, at 10, 22). The Court finds Plaintiff's design defect and failure to warn claims are expressly preempted and Plaintiff's manufacturing defect claim fails to state a claim for which relief can be granted. The Court further finds that all claims premised on Defendants' failure to report adverse events to the FDA are impliedly preempted.[3]

Express Preemption

The FDCA's Medical Device Amendments of 1976 (MDA) bar any state law requirement for medical devices which "is different from, or in addition to, any requirement" set by the FDA if that requirement "relates to the safety or effectiveness of the device". 21 U.S.C. § 360(k)(a). The Supreme Court held this statute bars tort claims challenging a medical device's safety or effectiveness in certain instances, and it established a two-prong test to determine whether a claim is preempted. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Tort claims of this nature are preempted if (1) "the [f]ederal [g]overnment has established requirements applicable to [the medical device]" and (2) the plaintiff's "common-law claims are based upon [state] requirements

3. The following analysis is also applicable as an alternative basis for dismissal for all three parties this Court dismissed *supra* for lack of jurisdiction, as Plaintiff brings the same claims against all parties.

with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.*

All medical devices which receive premarket approval fulfill the first prong of the test, as the premarket approval process "is [a] federal safety review" which imposes federal requirements on the product. *Id.* at 322-23. Under the second prong, a claim is barred if it is made under state law duties that are not "parallel" to federal requirements. *Id.* at 330. Some courts have phrased this as a "mirror and ceiling" rule: the state law must mirror the federal requirements, and the state law cannot break the "ceiling" of the federal law by imposing additional requirements. *See, e.g.*, *Mories v. Boston Sci. Corp.*, 494 F. Supp. 3d 461, 468 (S.D. Ohio 2020).

CooperSurgical argues Plaintiff is also required to specifically allege a violation of a particular federal regulation. (Doc. 40, at 12). Some federal courts in Ohio have required this. *See, e.g.*, *Schmidt v. Boston Sci. Corp.*, 2016 WL 1274824, at *3 (N.D. Ohio) (citing *Wolick-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)); *Mories*, 494 F. Supp. 3d at 471 (citing *Wolicki-Gables*, 634 F.3d at 1301). Others have held that at the motion to dismiss stage, as long as "it is clear that the allegations include claims that Defendant has violated FDA regulations, these claims can be maintained." *Hawkins v. Medtronic*, 909 F. Supp. 2d 901, 908 (S.D. Ohio 2012) (cleaned up). While Plaintiff replies that she need not cite a specific federal regulation for her claim to prevail, she cites cases which hold slightly differently. (Doc. 43, at 14, 18). For example, while a federal regulation must be cited, the regulation need not be "device-specific". *See, e.g.*, *Kodger v. Zimmer Biomet Holdings, Inc.*, 2017 WL 4348997, at *4 (N.D. Ohio). And while a federal regulation must be cited, a plaintiff need not "allege specific *defects* that violate the FDA standards" when such specialized knowledge is not available. *Brooks v. Sanofi-Aventis U.S., LLC*, 2014 WL 7272243, at *4 (S.D. Ohio) (emphasis added).

The Filshie Clips are a Class III medical device which received premarket approval. (Doc. 35, at 6). They therefore meet the first prong of the *Riegel* test. Whether Plaintiff's three theories of negligence – design defect, manufacturing defect, and failure to warn – are expressly preempted under § 360(k) depends upon whether Ohio law for each of these claims mirrors the federal requirements. *Riegel*, 552 U.S. at 322.

Design Defect

Plaintiff brings her design defect claim under Ohio Revised Code § 2307.75. (Doc. 35, at 16). This statute holds "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design . . . exceeded the benefits associated with that design." Ohio R.C. § 2307.75(A). Foreseeable risk is determined by factors such as:

> (1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;
>
> (3) The likelihood that that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer;
>
> (5) The extent to which that design or formulation is more dangerous than a resonably [sic] prudent consumer would expect when used in an intended or reasonably foreseeable manner.

Ohio Rev. Code § 2307.75(B). And associated benefits are determined by factors such as:

> (1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;

> (2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;
>
> (3) The nature and magnitude of any foreseeable risks associated with an alternative design or formulation.

Ohio Rev. Code § 2307.75(C). Additionally, an "ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the . . . ethical medical device provides adequate warning and instruction" under Ohio law. Ohio Rev. Code § 2307.75(D).

Plaintiff argues the Filshie Clips are defective in design because their propensity to migrate makes the "risk of harm exceed their claimed benefits". (Doc. 35, at 17). Plaintiff states failure by Defendants (including CooperSurgical) to correctly report migration rates to the FDA during the premarket approval process "allowed for the defective design to remain the same." *Id.* The issue of whether Defendants misled the FDA during the premarket approval process is essentially a "fraud-on-the-FDA" claim; these claims are better addressed in analysis of implied preemption under the FDCA.

As it stands, Plaintiff's design defect claim essentially argues that the Filshie Clip "should have been designed in a manner different than that approved by the FDA." *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 987 (N.D. Ohio 2017). Such claims are "the exact type of claim that is expressly preempted under § 360k(a)", as they are "a frontal attack on the risk/benefit analysis that led the FDA to approve the device" during the premarket approval process. *Id.* (citing *Aaron v. Medtronic*, 209 F. Supp. 3d 994, 1007 (S.D. Ohio 2016)). Because application of the Ohio law in this claim takes issue with, rather than mirrors, the federal requirements, thereby fulfilling both prongs of the *Riegel* preemption test, Plaintiff's design defect claim is preempted.

Manufacturing Defect

Plaintiff brings her manufacturing defect claim under Ohio Revised Code § 2307.74, which states "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same [specifications, formula, or standards]." (Doc. 35, at 18) (quoting Ohio Rev. Code § 2307.74). Plaintiff alleges broadly that the Filshie Clips used in her surgery "contained a condition or conditions, which Defendants did not intend, at the time the Filshie Clips left Defendants' control and possession", and that Defendants "[c]ontinu[ed] manufacture and sale of Filshie Clips with the knowledge that [] they were dangerous and not reasonably safe[] and fail[ed] to comply with FDA manufacturing regulations."(Doc. 35, at 18-19).

Plaintiff argues in response that as long her manufacturing defect is predicated on violations of "various FDA regulations related to manufacturing", the claim is not preempted. (Doc. 43, at 14). Plaintiff lists as examples 21 C.F.R. § 820.20, which regulations medical device manufacturing responsibility structure; 21 C.F.R. § 820.30, which states manufacturers of certain medical devices (including all Class III medical devices) must "establish and maintain procedures to . . . ensure that specified design requirements are met"; and 21 C.F.R. § 820.100, which lays out manufacturing error correction and prevention requirements. (Doc. 43, at 14, n.7).

Plaintiff is correct that in some cases, where a court "can not engage in a detailed comparison of the specific state and federal requirements at issue", but "it is clear that the allegations include claims that Defendant has violated FDA regulations, these claims can be maintained". *Mories*, 494 F. Supp. 3d at 472 (quoting *Hawkins*, 909 F. Supp. 2d at 905) (cleaned up). In other instances, however, courts consider such claims preempted where a plaintiff "asserts

no facts linking an alleged [manufacturing process] violation, recall, or FDA regulatory action to the injuries [she] claims that the specific device implanted . . . caused." *Warstler*, 238 F. Supp. 3d at 988.

This Court finds Plaintiff's vague allegations of manufacturing defect place her claim in the space described by *Mories*: there is not enough specificity in the claimed federal violations to determine whether they are paralleled by Plaintiff's state claims, but Plaintiff made clear in the amended complaint that such federal regulation violations caused her injury. But while Plaintiff's vagaries may save her manufacturing claim from being preempted, they ultimately fail to make a cognizable claim at all. The Court agrees with CooperSurgical's argument (Doc. 40, at 22) that these bare allegations amount to no more than "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555; *see also Anderson v. Boston Sci. Corp.*, 2013 U.S. Dist. LEXIS 22982, at *10 (S.D. Ohio) ("Plaintiffs did not allege a single specific manufacturing . . . defect in the stimulator or provide any factual basis from which the Court could plausibly infer that Defendant Boston Scientific violated FDA manufacturing, inspection or maintenance standards"); *Anthony v. Stryker Corp.*, 2010 WL 1387790, at *4 (N.D. Ohio) ("Anthony also did not plead any facts that would lead this court to plausibly infer that Stryker's noncompliance with FDA regulations led to his injury. Anthony's attempt to recast generalized deviations from 'manufacturing performance standards' as specific violations of federal regulations is insufficient to state a claim."). The Court therefore dismisses Plaintiff's manufacturing defect claim for failure to state a claim.

Failure to Warn

Plaintiff's failure to warn claim is brought under Ohio Revised Code § 2307.76, which provides that a product is defective by way of inadequate warning if, (1) at the time of its initial marketing,

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and]
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm[;]

or, (2), at post-marketing,

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A).

Plaintiff argues the Filshie Clip migration risk warnings were inadequate because (1) incorrect migration rates were reported to the FDA and (2) the language which "affirmatively advertised the safety of the Filshie Clip System . . . effectively downplay[ed] even the *de minimis* risk of migration or expulsion reported to the FDA." (Doc. 35, at 20). The former claim is another statement of Plaintiff's "fraud-on-the-FDA" claim, addressed in depth *infra*. The latter would require, in order to succeed, a holding that the FDA-required warning provided to Plaintiff was insufficient. The Sixth Circuit has held that "[a]ny claim, under state law, . . . that Defendant failed

to warn patients beyond warnings required by the FDA . . . would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." *Cupek v. Medtronic*, 405 F.3d 421, 424 (6th Cir. 2005) (citing *Kemp v. Medtronic*, 231 F.3d 216, 235 (6th Cir. 2000)).

Plaintiff argues her allegations "are based on information Defendants received *after* the FDA's approval of the medical device." (Doc. 43, at 15) (emphasis in original). The *Cupek* decision preempted "'failure to warn' . . . claims against Defendant based on 'information learned after FDA review [of the medical device].'" 405 F.3d at 422. Plaintiff's failure to warn claim is plainly preempted by 21 U.S.C. § 360(k) under Sixth Circuit case law.

Implied Preemption

Woven throughout Plaintiff's arguments is a claim that all Defendants deliberately withheld correct data on the rate of Filshie Clip migration from the FDA, either during the premarket approval process or after its approval. *See, e.g.*, Doc. 35, at 8-10; Doc. 43, at 15-16. Such a "failure to report adverse events" violates a requirement of the FDCA, but the FDCA does not provide a private right of action. 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States").

Plaintiff argues she does not assert a cause of action for failure to report adverse events, but rather uses "the violation of federal regulations as a measure of standard of care and as evidence of wrongdoing[] to support [her] state law claims". (Doc. 43, at 20). But when reliance on a failure to report adverse events "is a critical element in [a plaintiff's] case, [the plaintiff] would not be relying on traditional state tort law", even if the plaintiff states that is what she is doing. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001). Plaintiff indeed argues that she asserts only "well-recognized state tort claims in the Complaint." (Doc. 43, at 21). But an assertion

that Defendants did not properly report adverse events to the FDA is central to Plaintiff's claims in this case; she places this failure at the heart of the injuries she suffered. *See, e.g.*, Doc. 35, at 10 ("Plaintiff has suffered as a result of Defendants' failure to report adverse events involving the Filshie Clip"); Doc. 35, at 5 ("Defendants' failure to conform with the FDA requirements prescribed in the PMA and violations of relevant state and federal law form the basis of this lawsuit"). Because these "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted [sic] by, federal law", Plaintiff's claims are preempted by 21 U.S.C. § 337(a) and the *Buckman* holding. *Buckman*, 531 U.S. at 348.

Motion to Strike

Femcare additionally filed a Motion to Strike. (Doc. 58). Plaintiff opposed (Doc. 61), and Femcare replied (Doc. 62). Femcare seeks to strike Plaintiff's Exhibits A and B and her reference to an article not attached, all of which were included in her opposition to Femcare's motion to dismiss (Doc. 55), as they are "outside of the pleadings in this case and were improperly cited in opposing Femcare's 12(b)(6) motion." (Doc. 58, at 1). Plaintiff argues the exhibits and article were appropriately cited. (Doc. 61, at 3-4).

"[M]atters outside of the pleadings are not to be considered." *Weiner v. Klais & Co.*, 108 F.3d 86, 88 (6th Cir. 1997). The pleadings a court may consider include "the Complaint and any exhibits attached thereto, public records, items appearing in the record of the case and exhibits attached to the defendant's motion to dismiss so long as they are referred to in the Complaint and are central to the claims contained therein." *Bassett v. NCAA*, 528 F.3d 426, 430 (6th Cir. 2008).

Exhibits A and B attached to Plaintiff's opposition to Femcare's motion are transcript excerpts from "two depositions of Kevin Cornwell, director of Femcare and Chief Executive Officer of Utah Medical Products, Inc., taken in cases pending before the Southern District of

Texas and the District of Rhode Island." (Doc. 58-1, at 2). The referenced article is a 2001 medical journal article written by Dr. G. Marcus Filshie. *Id.* Femcare argues these materials "are not public records[,]were not previously in the case record[,] and[] were not attached to the Amended Complaint." *Id.*

As correctly observed by Plaintiff in her opposition, the Dr. Filshie article is cited in the Amended Complaint. (Doc. 35, at 9 n.2). While Plaintiff does not specifically reference the deposition transcript excerpts in her Amended Complaint, the content of the excerpts – Cornwell's testimony regarding his role, the composition and mechanics of Filshie Clips, and opinions regarding clip migration – are stated extensively in the Amended Complaint. *Compare* Doc. 55-1, at 5 ("yes, Femcare was well aware of clip migration"), *with* Doc. 35, at 12 ("[t]he knowledge Defendants have regarding the migration issues"); *compare* Doc. 55-2, at 2 ("[i]t's made of titanium, yes . . . and silicone") *with* Doc. 35, at 5 ("a titanium clip with silicone rubber lining").

Additionally, as evidenced by its analysis *supra*, the Court found no need to reference the article or the exhibits in order to make its decision on Femcare's motion to dismiss (nor any of the other three Defendants' motions to dismiss). Because the information to which Femcare objects was included in Plaintiff's Amended Complaint, and because the matter had no bearing on the Court's decision, Femcare's Motion to Strike is denied.

CONCLUSION

For the foregoing reasons, good cause appearing, it is

ORDERED that Defendant Cooper Companies, Inc.'s Motion to Dismiss (Doc. 38) be, and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendant Utah Medical Products, Inc.'s Motion to Dismiss (Doc. 39), be and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendant CooperSurgical, Inc.'s Motion to Dismiss (Doc. 40), be and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendant Femcare, Ltd.'s Motion to Dismiss (Doc. 52), be and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendant Femcare, Ltd.'s Motion to Strike (Doc. 58), be and the same hereby is, DENIED.

s/ *James R. Knepp II*
UNITED STATES DISTRICT JUDGE